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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,069	08/05/2003	Frank J. Bunick	MCP-222 DIV	7210

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EXAMINER	
BERKO, RETFORD O	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/635,069	BUNICK ET AL.
	Examiner	Art Unit
	Retford Berko	1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement: The Amendment filed 5/16/05 is acknowledged.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 6, 9-13 and 15-22 remain are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 09/002, 447 in view of Mapelli et al (WO 91/16043).

The instant claims are directed toward a composition comprising ibuprofen granules coated with hydro-colloid polymer or other non-hydrocolloid polymer. The co-pending Application (09/002, 447 by the same inventors) claims a composition comprising ibuprofen in liquid or tablet form in the absence of a hydro-colloid binder. Mapelli et al disclose (WO '043) ibuprofen composition comprising hydro-colloid binder and other non-hydrocolloid binders in order to minimize bitter taste of the drug.

As in the instant claims, it would be obvious to one of ordinary skill in the art to add hydrocolloid binders to ibuprofen composition in co-pending application (09/002, 447) in order to achieve the beneficial effect (i.e. reduced bitterness, more palatable drug) obtained in WO '043. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn toward the same invention wherein a composition comprising (isobutyphenyl)-proprionic acid (commonly known as ibuprofen) is coated with hydrocolloid polymer and in order to reduce the undesirable effects of the medicament.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 9 remain rejected as unpatentable under 35 U.S.C. 103(a) over Loew et al (US 5, 541, 227) in view of Mapelli et al (WO 91/16043) further in view of Humber et al US 5, 780, 046).

Loew et al (Patent '227) disclose a pharmaceutical composition comprising a racemic mixture of ibuprofen (col 6, lin 10-15, lin 50-60; col 7, Table 1; lin 60-65 and col12, lin 15-30).

Patent '227 does not teach the use of fumaric acid as excipients.

Mapelli et al (WO '043) disclose polymer-coated, granular pharmaceutical compositions comprising ibuprofen, fumaric acid, tartaric acid or citric acid as excipients (1-20 wt/%)---page 2, lin 25-30; page 6, lin 1-5 and page 12, lin claims 2-5). According to Mapelli, the invention provides a method of masking the undesirable taste of the drugs by coating with polymeric membranes (page 2, lin 25-30).

Huber et al (Patent '046) discloses ibuprofen composition comprising fumaric acid as excipient (col 16, lin 20-30) or other formulations comprising citric acid or malic acid (col 8, lin 40-65). Significantly, Huber et al also allude to the unpleasant, bitter taste normally associated with the racemic mixture of the drug (col 1, lin 15-20) and provide a motivation to overcome the undesirable effects of the drug through the use of formulations that are organoleptically

acceptable; such as chewable tablets comprising ibuprofen and fumaric acid (col 2, lin 50-65 continuing to colcol 3, lin 1-20 and col 16, example 23).

One of ordinary skill would have been motivated to prepare pharmaceutical composition comprising racemic mixture of ibuprofen—generally known to have unpleasant taste--and mask such unpleasant taste by coating with mpolymeric membranes and/or adding excipients such as malic acid, fumaric acid as disclosed in the prior art. One or ordinary skill would expect to obtain organoleptically acceptable compositions of ibuprofen that would more appealing and suitable to patient taste and thereby improve patient compliance in taking the medication. Therefore the invention as a whole would have been obvious to one of ordinary skill at the time it was made.

2. Claims 1-22 remain rejected as unpatentable under 35 U.S.C. 103(a) over Loew et al (US 5, 541, 227) in view of Mapelli et al (WO 91/16043) further in view of Reuter et al (US 4, 835, 187).

The claims are directed toward an oral composition comprising a racemic mixture of ibuprofen or derivative and 50-150 wt/% fumaric acid (or 60%, 7-13%). The claims are also directed toward the composition of ibuprofen wherein the drug are coated particles and comprise excipients and the polymeric coating is hydrocolloid. The claims are further drawn toward the composition in tablet, chewable dosage, liquid, suckable solid or semi-solid form; the composition reduces the burn sensation of ibuprofen.

As mentioned, Loew et al (Patent '227) disclose a pharmaceutical composition comprising a racemic mixture of ibuprofen (col 6, lin 10-15, lin 50-60; col 7, Table 1; lin 60-65 and col12, lin 15-30).

Patent '227 does not teach the use of fumaric acid as excipients and does not teach that ibuprofen drug particles are used for making the composition.

We discussed Mapelli et al (WO '043) above. WO '043 discloses the use of polymer-coating before granulation (page 4, lin 10), discloses the use of polymer for coating (page 4, lin 24, continuing to page 5, lin 1-5) and discloses the use of excipients such as fumaric acid (page 2, lin 25-30; page 5, lin 1-6; page 6, lin 1-5 and page 12, lin claims 2-5; and page 12, claim 2). WO '043provides a method of masking the undesirable taste of the drugs by coating with polymeric membranes (page 2, lin 25-30 and page 13, claim 10). WO '043 discloses formulations of the drug such as tablet, sachet and formulation that is easily disintegrated in the mouth (page 6, lin 10).

Reuter et al (Patent '187) is relied upon for the disclosure of powdered ibuprofen composition comprising cellulose and hydroxyethyl cellulose, sodium lauryl sulfate and fumaric acid (col 4, lin 1-10, col 5, Example 4 and Example 5). Significantly, Patent '187 discloses that the composition is taste neutral (col 3, lin 55-60 and col8, lin 10-15).

One of ordinary skill would have been motivated to prepare pharmaceutical composition comprising racemic mixture of ibuprofen—generally known to have unpleasant taste--and mask such unpleasant taste by coating with mpolymeric membranes and/or adding excipients such as malic acid, fumaric acid as disclosed in the prior art. One or ordinary skill would expect to obtain organoleptically acceptable compositions of ibuprofen that would more appealing and suitable to patient taste and thereby improve patient compliance in taking the medication. Therefore the invention as a whole would have been obvious to one of ordinary skill at the time it was made.

Response To Arguments

Applicant argues that there are no facts supporting examiners's reasoning for the Sec 103 rejection in that one of ordinary skill would not be motivated to prepare pharmaceutical composition comprising racemic mixture of ibuprofen- generally known to have an unpleasant taste- and mask such unpleasant taste by coating with polymeric membranes and/or adding excipients such as malic acid, fumaric acid because according to applicant, the Loew reference teaches away from the claimed invention and applicant is unable to understand how on the basis of Loew's disclosure, one of ordinary skill in the art would be motivated to use racemic ibuprofen in the method claims of the present invention.

In response, the instant claims are method claims drawn toward reducing the burning sensation of propionic acid derivative (ibuprofen). In giving the broadest interpretation for the claims, examiner takes the position that the method claims are inexorably linked to the composition claims because the final product, i.e. the ibuprofen formulation, has to taken by a patient in order to realize the benefits, if any of the drug; --namely the reduction in the burning sensations (unpleasant taste).

With this as the background, the Sec 103(a) obviousness rejection is maintained given the disclosures in prior art cited as explained supra. Respecting this issue, Mapelli specifically discloses a process or method for masking the taste of ibuprofen to reduce or prevent dissolution of the drug in the oral cavity by coating the granulate core during preparation of tablets (Patent '711, col 2, lin 24-45; col 3, lin 1-5, col 4, lin 21-25, lin 51-60; col 5, lin 1-10 and col 6, lin 40-46). Furthermore, Reuter et al discloses improvement in ibuprofen dosage form when the drug is

spray-dried with taste-neutral cellulose materials or admixtures thereof (Patent '187, col 6, lin 60-68, continuing to cols 7-8. Finally, the disclosures in both Mapelli and Reuter are reinforced by the relevant inferential disclosure in Humber—that taste masking of ibuprofen may be achieved by coating the drug with suitable materials, preferably material that cannot be easily punctured by chewing (Patent '046, col 2, lin 44-63). Therefore, the instant claims drawn to a method of reducing burning sensations of proprionic aci derivative i.e. ibuprofen by coating the drug with fumaric fumaric acid and other excipients would have been prima facie obvious to one of ordinary skill at the time it was made given that the prior art cited have used the excipients for the purpose of eliminating or preventing unpleasant taste of ibuprofen.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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